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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/972,772	10/05/2001	Gary L. Olson	PPI-106CP	4878

959 7590 04/09/2004

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,772	OLSON ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004 and 06 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43 and 45-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43 and 45-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/6/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election without traverse of the species SEQ ID NO:16 in the response filed March 9, 2004 is acknowledged.

In order to expedite prosecution of this application, it is recommended that Applicants delete the non-elected species from claims 28 and 37 in the response to this Office action.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The Sequence Listing filed June 17, 2003 was not accompanied by a statement that the sequence listing includes no new matter as required by 37 CFR 1.825(a) and (b). Correction is required.

The Sequence Listing filed June 17, 2003 was otherwise approved by STIC for matters of form.

3. The disclosure is objected to because of the following informalities: The status of the parent application at page 1, line 8, of the specification should be updated. The Tables at page 43 of the specification need to be amended in order to reflect the new SEQ ID NOS as set forth in the Sequence Listing filed June 17, 2003. Appropriate correction is required.

4. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 21, the word "and" should be inserted before formula (IX) so that standard Markush terminology is used.

5. Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claim 20 recites that D can be a cyclic C_{1-6}-alkyl. However, claim 15, upon which claim 20 depends, does not indicate that D can be a cyclic alkyl.

6. Claims 1-28, 37, 38, 48, 53, 54, and 57-60 are objected to because of the following informalities: At claim 1, line 20, the period after "thereof" should be deleted. At claim 2, line 2, the second occurrence of "Z is" should be deleted. Claims 15 and 22 do not end with periods. At claim 21, last line, the end parenthesis after "amino" is unmatched. At claim 28, line 2 (first occurrence), and claim 37, line 2 (second occurrence), "the" should be deleted. At claim 38, page 10 of the amendment filed November 6, 2003, line 5, and claim 48, page 13, line 21, there is an unmatched end parenthesis after "enyl". At claim 38, page 10, line 8, and claim 48, line 24, the beginning parenthesis before "3-" does not match the end bracket after "enyl". At claim 38, page 10, line 13 - page 11, line 4, and claim 48, page 14, lines 5-18, the ID#'s should be not occur in the middle of the compound names. Claim 51 ends with a colon rather than with a period. At claim 58, line 3, "a" (first occurrence) should be changed to "an". At claim 59, line 2, "to" should be inserted before "said". Appropriate correction is required.

7. Applicant is advised that should claim 49 be found allowable, claim 50 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 49 and 50 are identical in scope.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-43 and 45-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of U.S. Patent No. 6,548,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to combine the claimed active agents of the '477 patent with pharmaceutically acceptable carriers because it is routine in the pharmaceutical arts to combine therapeutically active agents with pharmaceutically acceptable carriers for ease of storage, transport, measurement, and administration. With respect to instant claims 53-56 and 60, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '477 patent in the form of controlled release compositions and in the form of microcapsules because these are conventional forms for pharmaceutically active agents and would not have been expected to interfere with the activity of the claimed active agents. With respect to instant claims 57 and 58, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '477 patent with other known active agents used to treat the same diseases, including those specified in instant

claim 58, because it is routine in the pharmaceutical arts to administer multiple drugs intended to treat the same underlying disease, and because it is prima facie obvious to combine two components, each of which is used individually for the same purpose. See In re Kerkhoven, 204 USPQ 1069, 1072 (CCPA 1980).

9. Claims 1-43 and 45-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-65 of copending Application No. 10/001,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to combine the claimed active agents of the '945 application with pharmaceutically acceptable carriers because it is routine in the pharmaceutical arts to combine therapeutically active agents with pharmaceutically acceptable carriers for ease of storage, transport, measurement, and administration. With respect to instant claims 53-56 and 60, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '945 application in the form of controlled release compositions and in the form of microcapsules because these are conventional forms for pharmaceutically active agents and would not have been expected to interfere with the activity of the claimed active agents. With respect to instant claims 57 and 58, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '945 application patent with other known active agents used to treat the same diseases, including those specified in instant claim 58, because it is routine in the pharmaceutical arts to administer multiple drugs intended to treat the same underlying disease, and because it is prima facie obvious to combine two components, each of which is used individually for the same purpose. See In re Kerkhoven, 204 USPQ 1069, 1072 (CCPA 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-38 and 49-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-58, 60, 62, and 71-90 of copending Application No. 10/138,935. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to combine the claimed active agents of the '935 application with pharmaceutically acceptable carriers because it is routine in the pharmaceutical arts to combine therapeutically active agents with pharmaceutically acceptable carriers for ease of storage, transport, measurement, and administration. A difference in intended use does not impart patentability to composition claims where the claimed composition is otherwise anticipated by or obvious. With respect to instant claims 53-56 and 60, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '935 application in the form of controlled release compositions and in the form of microcapsules because these are conventional forms for pharmaceutically active agents and would not have been expected to interfere with the activity of the claimed active agents. With respect to instant claims 57 and 58, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '935 application patent with other known active agents used to treat the same diseases, including those specified in instant claim 58, because it is routine in the pharmaceutical arts to administer multiple drugs intended to treat the same underlying disease, and because it is prima facie obvious to combine two components, each of which is used individually for the same purpose. See In re Kerkhoven, 204 USPQ 1069, 1072 (CCPA 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

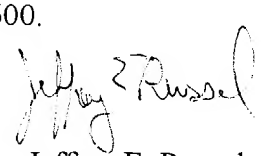
11. Claims 1-43 and 45-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/429,174. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to combine the claimed active agents of the '174 application with pharmaceutically acceptable carriers because it is routine in the pharmaceutical arts to combine therapeutically active agents with pharmaceutically acceptable carriers for ease of storage, transport, measurement, and administration. With respect to instant claims 53-56 and 60, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '174 application in the form of controlled release compositions and in the form of microcapsules because these are conventional forms for pharmaceutically active agents and would not have been expected to interfere with the activity of the claimed active agents. With respect to instant claims 57 and 58, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '174 application patent with other known active agents used to treat the same diseases, including those specified in instant claim 58, because it is routine in the pharmaceutical arts to administer multiple drugs intended to treat the same underlying disease, and because it is prima facie obvious to combine two components, each of which wis used individually for the same purpose. See In re Kerkhoven, 204 USPQ 1069, 1072 (CCPA 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. The Griffith et al article (Proc. Natl. Acad. Sci., Vol. 95, pages 15183-15188) has been carefully considered but is not deemed to anticipate or suggest the instant claimed invention. In particular, the Griffith et al article does not teach its compound 8 in combination with a pharmaceutically acceptable carrier as part of a pharmaceutical composition, and does not teach or suggest that its compound 8 has pharmaceutical activity. Accordingly, there is no motivation to formulate compound 8 of the Griffith et al article as part of a pharmaceutical composition.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 7, 2004